THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes the

THIRTY-SECOND MEETING

ADVISORY BOARD ON

RADIATION AND WORKER HEALTH

DAY THREE

MALLINCKRODT SEC PETITION

The verbatim transcript of the Meeting of the Advisory Board on Radiation and Worker Health held at the Westin Hotel, St. Louis, Missouri, on August 26, 2005.

C O N T E N T S

August 26, 2005

TRANSCRIPT LEGEND

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ROESSLER, Genevieve S., Ph.D.
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SPEAKERS

(in order of appearance)

MR. STUART HINNEFELD, NIOSH
MS. DENISE BROCK, MALLINCKRODT
DR. DAN MCKEEL, VILLAGE IMAGE NEWS
DR. ARJUN MAKHIJANI, SC&A

STAFF/VENDORS

LASHAWN SHIELDS, Committee Management Specialist, NIOSH
STEVEN RAY GREEN, Certified Merit Court Reporter

AUDIENCE PARTICIPANTS

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BLOSSER, FRED, NIOSH
BROCK, DENISE, UNWW/MALLINCKRODT
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DOWNS, DEB, TITAN
DUNGAN, JUDITH, SENATOR BOND'S OFFICE
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MAKHIJANI, ARJUN, SC&A
MAURO, JOHN, SC&A
MCKEEL, DAN & LOUISE, VILLAGE IMAGE NEWS
MILLER, RICHARD, GAP
MITAS, JIM, OFFICE OF CONGRESSMAN AKIN
NUGENT, MARY, GAO
PRESLEY, LOUISE S., WIFE OF ROBERT PRESLEY
SCHWENNESEN, CLARENCE, UNWW
SCHAEFFER, D. MICHAEL, SAIC
SCHNEIDER, MARILYN, UNWW
STRAPES, FLORENCE, MALLINCKRODT
TENFORDE, THOMAS, NCRP
TOOHEY, RICHARD, ORAU
WILDHABER, SANDRA, MALLINCKRODT
ZIEMER, MARILYN

P R O C E E D I N G S

(8:40 a.m.)

WELCOME AND OPENING COMMENTS

DR. ZIEMER: We're going to reconvene our session here this morning. A couple of the normal housekeeping items. I remind you, again, to please register your attendance in the registration book if you've not already done that.

We welcome this morning to the assembly Judith Dungan. Did I pronounce that correctly, Judith?

MS. DUNGAN: That is correct.

DR. ZIEMER: Good. And Judith is with Senator Chris Bond's office and is with us here this morning, so we're pleased to have Judith here today.

Lew Wade has a couple of items to bring to us. Lew?

DR. WADE: Thank you, Paul. Yeah, today is the day that we -- we again take up the vote on the Mallinckrodt SEC petition, the latter years. And I just wanted to, as the Designated Federal Official, make some comments about that process.

I talked to you the last time about

understanding the fact that there will always be tension between the passage of time, the need to be timely and the need to be complete in our scientific deliberations. That'll be a tension this Board faces in everything it does. We've certainly faced it as it relates to the Mallinckrodt SEC petition.

I mean as the Designated Federal Official I don't think we can leave St. Louis without a decision on that petition this time. I appreciate the process we've gone through. I think it has certainly added value, but it also has been a very difficult process for petitioners and for claimants. And from my perspective as the Designated Federal Official I think we need to look at the material on hand today and move to making a decision.

My agency values timeliness in what it does. It also values the need to be complete, and we understand that tension. We'll address it differently in different situations. I think the time has come now for us to -- this Board to make a recommendation on the Mallinckrodt SEC petition.

DR. ZIEMER: Thank you very much, Lew, for that

timely reminder.

We're going to move directly into the issue of the Mallinckrodt SEC petition, and we have two, I think, semi-brief presentations, one from NIOSH and one from the petitioners.

In the absence of Larry Elliott, who we indicated was facing some health problems this week, Stu Hinnefeld from NIOSH is going to make the presentation. And here's Stu approaching the mike. Stu, you can use either one, whatever is -- whatever you're com-- yeah, use this one so you're facing everybody. That will be fine.

PRESENTATION FROM NIOSH

MR. HINNEFELD: Good morning everyone. I'll be -- I'll be brief today. The -- we have -- we have not prepared an amendment -- an amended petition evaluation report or revised petition evaluation report, and so any presentation I would present would just be the presentation that's been presented to the Board in the past. So I don't have a slide show presentation.

I would like to say that we have worked very hard within the framework established by the Board with our -- with the Board's contractor,

SC&A. A lot of people worked very hard on this to get the best science we can to resolve the questions that have been raised and that's been the question at hand. And so we have done that and that's what we expect to do, and I think that's what should be expected of us is to work hard to resolve the scientific questions in front of us.

In this particular case, clearly it's made things very difficult and we understand that, and to engage in a process of SEC -- of petition site profile, site profile evaluation review while there is an SEC petition for that affected site being considered by the Board is clearly an extremely difficult circumstance and we certainly recognize that. And we would like to propose that for future actions I would like the -- I would think that NIOSH and the Board could perhaps work together for a set of procedures or processes just to make sure that we don't find ourselves in a similar situation on other petitions at other times.

That concludes my comments.

DR. ZIEMER: Thank you, Stu. While you're at the podium let me ask if any of the Board

members have specific questions for you at this point. We may as we get into the debate shortly, but any -- any immediate questions for Stu Hinnefeld?

(No response.)

Okay. Thank you very much, Stu. Then let's move to the petitioners and begin with Denise Brock, and then any others. Denise, do you have others also who will be making statements for the petitioners or --

MS. BROCK: (Off microphone) (Unintelligible)

DR. ZIEMER: Okay. All right, fine.

PRESENTATION FROM PETITIONERS

MS. BROCK: Good morning everybody. Before I begin today I would just like to point out that subsequent to the issuance of the NIOSH regulations and procedures in 2004, the FY '05 Labor HHS Appropriations Act restated the need for both timely decisions and approval of SECs when records documenting internal or external dose were missing.

The committee strongly encourages NIOSH to expedite decisions on petitions filed under the procedures for designated classes of employees as members of the Special Exposure Cohort, 42

CFR Part 83. It was Congress' intent in passing the EEOICPA -- or, I'm sorry, the Energy Employee's Compensation Act of 2000, to provide for timely, uniform, and adequate compensation for employees made ill from exposure to radiation, beryllium, and silica while employed at the Department of Energy nuclear facilities or while employed at beryllium vendors and atomic weapons employer facilities.

The committee encourages the Department to recognize that in situations where records documenting internal or external radiation doses received by workers at the specific facility are of poor quality or do not exist, that workers should promptly be placed in a Special Exposure Cohort.

I would first like to thank the members of this Advisory Board for their continued efforts in this process. I want to thank you for exercising such patience, diligence, and integrity. I would also like to extend that same thanks to SC&A, as well as to NIOSH. And, again, before I begin with my statement, I would also like to say that Senator Kit Bond

has been in touch with me and sends his regrets that he is unable to attend this particular meeting. He's also asked me to state that he stands by his opinion that dose reconstruction cannot be done, and that it further supports the request to approve the Special Exposure Cohort petition for the Mallinckrodt workers. He wants it stated for the record that the former Mallinckrodt workers are part of an endless bureaucratic process.

Senator Bond has a staff member here today, Judy Dungan. I believe that Dr. Ziemer or Dr. Wade had mentioned Judy, and I want to thank her personally as well for being here again, and I would like to recognize all of the Congressional delegation from Senator Talent's office, Congressman Akin and their staff, actually for their continued support in our plight.

Most recently, or at least at the last Board meeting, I've been able to listen to and/or participate in workgroup meetings, conference calls, et cetera, that were pertaining to Mallinckrodt and this SEC petition. I have seen and heard firsthand the amount of effort

and work that has been done by all entities and I would like to commend each and every one of you. There has been a tremendous amount of work all the way around this thing. This is a very difficult process.

I understand that Mallinckrodt is actually the first SEC petition to actually been put in this way, and so maybe this was just a big learning process for all of us and I just appreciate all the work that was put into it. I think the work was -- was not for naught. I think that this could help future cohort petitions, and I greatly appreciate that. I think this was long, but at the end of this I think would be extremely helpful.

Several days ago I prepared a statement and as you will see I've prepared something new, it's actually a notebook, it's not typed. Today I would like to start by giving some chronology. In July of 2004 I filed this SEC petition. It qualified on or about the 180-day mark. An SEC evaluation report came in.

In February, 2005, we all met at the Adams Mark Hotel here in St. Louis, and as I'm sure you all remember, you voted to grant the SEC status

for my workers from 1942 to '48. I again want to thank you for that. I greatly appreciate that and I know the claimants do.

But at that same meeting NIOSH, at the last minute, the 11th hour and without knowledge or review of the petition -- petitioner, myself, or the Board, stated that they had five or six boxes of data which had not been gone through and a 33-page memo which they claimed to have had a couple of months, all of which needed to be reviewed and all of which later failed to support what they had contended.

NIOSH also stated that although the SC&A review of Rev. 0 was complete, it was obsolete because Rev. 1 had already been started. NIOSH also stated that the TBD in place in February would allow them to do dose reconstructions based on uranium-driven models supplemented by radium dose. The Board voted to table the vote.

Then in April we all went to Iowa, and due to reprioritization or due to some unforeseen things happening, the site profile review was still not complete and, again, this was through no fault of SC&A. This was just something that happened, but again, it was tabled. NIOSH

still contended that this model that was in place would allow them to do dose reconstruction.

The next meeting moved to July, and I think you all remember that. We were at the Chase Hotel, again in St. Louis. Again, NIOSH claimed and stood firm in their ability to do these dose reconstructions with the present method. So sure they were that they claimed to be able to finish all of these Mallinckrodt cases within four months. Stanford Cohen and Associates had their review, and Dr. Makhijani asked how NIOSH was going to implement this toolbox. NIOSH was told to prove that they could do this.

And here we are again in St. Louis August, 2005. When the Board requested clarification they got an entirely new method from NIOSH. Now radionuclides which were once considered trace, like thorium, protactinium, and actinium, are now the dominant dose.

SC&A gave a report August 16th to the Board. This outlined yet further improvements that were needed. And between August 16th and the 23rd a vast amount of new data has been sprung on the Board, data that I as a petitioner and

you as a Board again have not reviewed, data that has not been analyzed. This is again and another -- I'm sorry, this is again another 11th hour tactic, and whether intentional -- intentional or not, has become a pattern and practice. It's a technique. None of this was passed out to me, to the public, or to the Board.

Some may call this real-time science. I call it sandbagging. This is becoming an open-ended process. This never has seemed like a level playing field.

I, as well as the Board, are at a distinct disadvantage. I've mentioned this for the record before. These tactics of dumping new data and information, new methods, new memos, et cetera, all of which are never before seen by the petitioner or the Board, or analyzed for that matter, is very poor practice and procedure. It's setting a poor precedent.

I'm not dealing with living documents. I'm dealing with a moving target. We are now at our fourth Board meeting regarding this petition. We've had four audit reports, Rev. 0 and two or three supplements to Rev. 1, four

subgroup meetings and numerous teleconference. Should we have a fifth audit report, a fifth meeting? Should we expect that every time we turn around, at the 11th hour we have new discovery, new vast data, a new process; or should an SEC petition be denied when we have significant uncertainties, numbers that are just turned in, missing data, unanalyzed data, and a complete 180-degree turnaround from six months ago.

The SEC evaluation is still on the table today, or better or best yet, approve this SEC petition because there are significant uncertainties coupled with feasibility issues. SC&A and the Board have spoke to the scientific issues, I don't need to reiterate that, the record's been laid. But I will speak to the feasibility issues as I started this.

There are three areas of feasibility. Number one would be technical, when relevant records may be lacking or not exist altogether. NIOSH does not have any dose on Plant 6 for raffinates. Some datapoints are missing, some data are not legible, et cetera.

Costs. When you may be able to construct dose

but would be cost prohibitive to do so. It is costing $80-$100 per hour for contractors who have spent untold hours to develop and revise site profiles, and the auditor continues to find problems, problems that need to be corrected before this can be done. We now have people or NIOSH has staff in Germantown recapturing data. This list could go on and on.

And, number three, the issue of time or timeliness. This might take so long to reconstruct dose for a group of workers that they would all be dead before we have an answer that could be used to determine eligibility. Many Mallinckrodt claimants are already survivors. The few living workers, Mallinckrodt workers, deserve an answer before they die.

And after almost four years to finalize regulations for Special Exposure Cohorts and another 13 months to assess my petition filed in July of 2004, NIOSH has far exceeded time contemplated by Congress for Special Exposure Cohort petition processing. Any more time expended on this or to extend this any longer

would be to reconstruct Congressional intent. I think that Stu Hinnefeld had mentioned this, but I understand this SEC evaluation report that was given in February is what is on the table today. I ask the Board to please vote to approve my Special Exposure Cohort petition for this group of brave workers, my workers of 1949 through 1957. Please give them the peace and the justice that they so deserve. Thank you.

DR. ZIEMER: Thank you, Denise. And before you leave the podium, let -- let me ask if any Board members have immediate questions for Denise?

(No response.)

Okay. Thank you. Then Dan McKeel is --

MS. BROCK: Dr. McKeel, I think, wanted to make a quick statement.

DR. MCKEEL: I'll be very brief. Thank you for letting me address you. Again, I'm Dan McKeel. I'm a retired pathologist and a physician. And today the Board has another opportunity to vote the Mallinckrodt 1949 to '57 SEC up or down. Wanda Munn's motion to deny the Brock petition is on the table. I believe the credibility of this Board will hinge on the vote. The

difficult decision is whether or not to accept NIOSH's claim it can reconstruct doses under 42 CFR 83 guidance. For me, as a scientist who has been awarded many competitive federal grants, I do not believe the aggregated science proposed by NIOSH passes the 42 CFR test of being able to be accurate and to fairly reconstruct or even to accurately bound radiation doses for the Mallinckrodt '49-'57 class of workers.

This class of people have certainly had their health harmed at MCW, at the St. Louis Airport site and at the Latty Avenue work sites. Once again I urge the Board to vote for the MCW SEC0012.2.

My reasons for feeling the way I do have been given in detail before, but here is a summary of my reasoning. At least 107 Mallinckrodt 1949 to '57 EEOICPA claims still await dose reconstructions. This is prima facie evidence that NIOSH cannot do what it must do, perform DRs in a timely manner. No best estimate MCR (sic) DRs have been done to date.

The CER database is limited and biased and encompasses only white male workers, who are

only about 70 percent of the total Mallinckrodt workforce. Women and minorities are excluded. The HASL database, which Mr. (sic) Neton describes as the gold standard, is just being reconstructed. Mark Griffon has found discrepancies between the MCW raw data sheets and the HASL database. Why is such late-breaking news, why is this unfinished business just being taken care of?

NIOSH largely abandoned daily weighted averages to determine intakes and now relies on a 20 percent sample of breath radon. This is too small a sample to provide valid bounding dose data and thus fails to meet the prime 42 CFR 83 test. They have offered to the Board an approach to DR, not completed actual Mallinckrodt best-estimate dose reconstructions.

The Weldon Spring 053 site profile was finally approved between June 24th and 26th of this year. It has not been presented to the Board or reviewed by SC&A. Data therein is crucial to performing Mallinckrodt dose reconstructions in settling claims. Why? Because the majority of Mallinckrodt workers were employed at both

the downtown and the St. Charles County sites. Final point. SC&A and NIOSH have not fully resolved their six points of issue between the last meeting of this Board and this meeting. Significant differences remain to be worked out.

For all these reasons and many more, including adherence to fairness and due process, the Board should today recommend SEC status for the 1949-1957 class of Mallinckrodt Uranium Division workers. Thank you very much.

DR. ZIEMER: Thank you, Dr. McKeel. And, again, let me ask if any Board members have immediate questions.

(No response.)

Denise, yes, a follow-up?

MS. BROCK: (Off microphone) (Unintelligible)

DR. ZIEMER: Sure, that's fine. Dr. Makhijani has asked for an opportunity to address an issue that was before us on the floor yesterday and just one item, I think, either to correct or clarify.

PRESENTATION FROM SC&A

DR. MAKHIJANI: Thank you, Dr. Ziemer. Yesterday I -- and in my presentation I had

said that the calculated value for the AM-7 area of air concentrations which NIOSH proposes to use as one of the bases for dose calculations in the thorium areas, was the average. And I misinterpreted the text that was sent to us by NIOSH in the pressure cooker. What NIOSH had said, on page 136 of your report at the top, in the first paragraph there, first full -- big paragraph, said, (reading) the area air concentrations used in this analysis are about a factor of 2 higher than the measured air concentrations exposures in areas associated with the AM-7 raffinate.

Now, I interpreted that phrase to -- to -- to mean average, but Jim Neton told me yesterday that it was the 95 percentile of the average daily weighted numbers that they had gathered. And he shared his spreadsheet with me last night, which I looked at very briefly with his assistance, and I agree that that's what they've done. There's a page in the report which will need to be corrected and we will send you a corrected page.

My one observation from looking -- or two observations to share with you from looking at

Dr. Neton's spreadsheet is that -- obviously it's a very quick look that I took. I don't believe it corresponds to the method that SC&A had recommended for 95 percentile air concentrations in our April report to you, and I did note that there were some years for which there was no data, which is why I think '50 to '57 has been aggregated. Dr. Neton told me that there are data for these years, it's -- there's just a methodological illustration that -- which was the reason for the gaps, it's not that the data may not exist. And obviously this is an issue that we have -- we have not reviewed because last night was the first time that I saw this. But I did want most importantly to put that correction into place and we will send you the corrected page. Thank you very much. Sorry about that.

GENERAL DISCUSSION

DR. ZIEMER: Thank you. Uh-huh. Now Board members, we'll open the floor for general discussion. You have two options before you. One is to move immediately to the -- the action. The other is to deal with any questions or issues that you'd like to discuss

before we move to an action. And the action possibilities are, one, to remove from the table the previous motion. You also obviously have the option of not removing it from the table, which then would require a different motion.

Any comments or questions in general? Jim?

DR. MELIUS: I would like to make a motion, and I think this will also provide the basis for discussion of -- of the issue. So it doesn't necessarily expect quick resolution, but Mark Griffon and I have worked on a motion and I believe there are copies available.

DR. WADE: Would you like me --

DR. MELIUS: Yeah. And this would be a motion for the Board to approve the SEC petition, and it's in the same format that we've done with our earlier letters. In fact, much of it is -- will be quite familiar to Board members since it's there. And I think it's easiest if we wait for the copies to be made available rather than for me to try to read it here.

DR. WADE: The copies are being made.

DR. ZIEMER: We probably need to have it read for the record in any event, so why don't you

for procedure read it, then we'll have -- by then we'll have the copies.

DR. MELIUS: I move the following (reading): The Board recommends that the following letter be transmitted to the Secretary of Health and Human Services within 21 days. Should the Chair become aware of any issue that in his judgment would preclude the transmittal of this letter within that time period, the Board requests that he promptly inform the Board of the delay and the reasons for this delay, and that he immediately works with NIOSH to schedule an emergency meeting of the Board to discuss this issue.

The letter reads as follows (reading): The Advisory Board on Radiation and Worker Health (the Board) has evaluated SEC Petition 00012-2 concerning workers at the Uranium Division of the Mallinckrodt facility under the statutory requirements established by EEOICPA and incorporated into 42 CFR Sec. 83.13(c)(1) and 42 CFR Sec. 83.13(c)(3).

The Board respectfully recommends a Special Exposure Cohort be accorded to all Department of Energy employees or its contractor or

subcontractor employees who worked at the Uranium Division of the Mallinckrodt Destrehan facility from 1949 to 1957 and whom were employed for a number of work days aggregating at least 250 work days occurring under this employment, in combination with work days of employment occurring within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC.

(Reading) This recommendation is based on the following factors: Number one, these workers were employed at a facility that processed materials during the early time period for the production of nuclear weapons. Radiation monitoring methods for all isotopes were under development at that time leading to significant gaps in the monitoring of these workers in comparison to current monitoring programs. Number two, while there are ample monitor data for some exposures, such as uranium and radium, data on exposures critical for accurate individual dose reconstruction are sparse. For important exposures such as thorium, actinium, and protactinium, there's relatively little

information available. The evaluation of these exposures -- of these isotopes is critical in reconstructing the organ doses for individual workers due to their substantial contribution to those doses. NIOSH has not yet demonstrated that the sparse information currently available are adequate to conduct individual dose reconstructions with sufficient accuracy. Number three, the available monitoring do not adequately characterize high exposure areas in the facility, leading NIOSH to attempt to extrapolate exposures using data from other areas. For example, there's not been an adequate assessment of the use of the daily weighted average -- excuse me, let me -- I'm actually reading from the wrong version of this. I apologize. Let me go back.

MR. GRIFFON: Are they copying the right version?

DR. WADE: They are copying it right now.

DR. MELIUS: They are copying the right one, yeah. I apologize to everybody.

DR. WADE: Just give me one minute and I'll get the copies.

DR. MELIUS: Okay, point number two. Point

number three -- let me go through -- start with the second point. Point number two, (reading) There is relatively little information available for estimating thorium, actinium, and protactinium. NIOSH's approach to dose reconstruction no longer relies on individual monitoring, but rather plant-wide air monitoring data, which is itself not even isotope specific. These data have to be converted into isotope-specific activity using residue fraction points which have not been validated. As such, NIOSH has not demonstrated that it can conduct individual dose reconstruction with sufficient accuracy. Point number three, while there are many internal exposure monitoring records for uranium and some for radium, there are no individual bioassay records for Plant 6 workers for high consequence isotopes extracted from the pitchblende ores and contained in the AM-7 and Sperry cake residues (thorium 230, actinium 231, and protactinium 227). There are only bioassay data for two months in March and April 1955 for the Plant 7E workers (thorium recovery operations) although operations continued in

1956 and 1957.

Next point, there are serious concerns about the lack of a method to adjust for the angle of incidents of external dose monitoring. This adjustment has a significant impact on the interpretation of the monitoring data and a final method needed for individual dose reconstruction is not yet available.

Next point. There are concerns about the validity of the radon breath data being used for dose reconstruction. Radium intakes based on radon breath data were taken from a secondary data source, and they have not been validated against source data. In response to questions about the validity of the data, NIOSH has just started an effort to obtain the data from the original records. This effort has not been completed and the Board has not been able to evaluate -- valuate the results of this effort.

Next point. The Board has reviewed data which confirms that radiation exposures of the Mallinckrodt facility during the time period in question could have been endangered the health of members of this class.

The Board has been deliberating for over six months on the Mallinckrodt SEC petition for the period 1949 to 1957. There have been four separate audit reports, four board meetings, four subcommittee or working group meetings, and countless conference calls and memos. NIOSH staff, the staff of their contractor, and the contractor for the Advisory Board have spent hundreds of hours working on this effort. Despite many meetings and two years of work on the site profile for the site, new data continues to emerge on the site including some first revealed to the Board during this most recent meeting. Efforts to find new data on the site could continue for years.

However, the Board also recognizes the need to make timely decisions. EEIOCPA requires that this program should produce a defensible radiation dose reconstruction in a reasonable period of time, and Congress has recently reinforced this objective in the FY '05 Defense Authorization Act and the Labor HHS Appropriations Act.

Based on these considerations, the Board recommends that this Special Exposure Cohort

petition be granted. It should be noted the Board believes that the exposure information available is adequate for the reconstruction of external exposures, and where appropriate for specific types of cancer, for example, skin, these -- those individual doses can be reconstructed.

And then final paragraph, enclosed is supporting documentation from the Advisory Board meeting held August 24-26, 2005 in St. Louis. This documentation includes transcripts of public comments on the petition, copies of the petition, the NIOSH review thereof, and related documents distributed by NIOSH and the petitioners.

And that's it.

DR. WADE: Just a minute.

DR. ZIEMER: You've heard the motion. Let me ask if -- before you get the printed copy, does anyone wish to second the motion?

MR. OWENS: I'll second the motion, Dr. Ziemer.

DR. ZIEMER: Leon has seconded the motion. We will pause just a minute till we --

DR. WADE: I also want to make sure Mike Gibson is at the table, so let me...

(Pause)

DR. ZIEMER: Okay, are there copies -- there are copies being run for the members of the public as well?

DR. WADE: (Off microphone) (Unintelligible)

DR. ZIEMER: Okay, this motion is now open for discussion. I'd like to -- just procedurally like to -- whoever -- okay, Gen Roessler will be first, and we will alternate. If someone speaks for the petition, then I will ask if there's any that wish to speak against and then we'll alternate. Dr. Roessler, you want to --

DR. ROESSLER: I'm not going to speak either for or against the motion at this -- at this time. I would just like to make a few comments.

DR. ZIEMER: Sure.

DR. ROESSLER: I think that Jim's motion is very compassionate and very persuasive. The thing I think we should keep in mind, though, is that we've been definitely on a learning curve. I think the Board has been at a disadvantage in not really having a clear definition on what we mean by "adequate information to do sufficient dose

reconstruction." That's -- that's been my problem is where do we draw the line, and I'm not sure that it's clear in my mind yet. Maybe it has to be done on an individual basis, but I think we would -- in the future we really need to address that.

The other thing that's on my mind right now, and Denise mentioned this and I think this was the Congressional intent, that as we go through this process we have to remember that it's uniformity. We have to be uniform in our decisions. I think we need to think about equity for the claimants, the claimants on the SEC petitions and also the claimants who don't go through that process. I think in fairness to these claimants, that's what we really need to think about right now is what we do here -- we have to think of equity.

DR. ZIEMER: Okay, thank you. Dr. Melius?

DR. MELIUS: Yeah, I'd like to respond, and I would agree with Gen's comments, that we've been approaching this without very tight criteria because we've not been provided with that, and I think NIOSH has also been struggling with sort of what is the best

approach for evaluating SEC petitions, what kind of information and how to, you know, formulate and present that information to us in order for us to make a recommendation. And I would agree with you that I think we've been doing sort of a case law approach where we deal with each one as, you know, best we can. I think we've handled them fairly so far, but the delays in this one I think illustrate some of the problems with that approach, for both of us and for NIOSH in evaluating these.

And I would certainly think that we should -- I think we need to deal with this petition and I think we need to deal with it today; however, I think we also -- it would be helpful if we have time today, or if certainly not today at our next meeting, that we discuss how to better handle these in the future. We've talked about that in the past. Stu mentioned in his talk. I mean, we've made a recommendation to -- or I shouldn't say "we." I made a recommendation in discussion with Larry a long time ago how the need for an SEC site profile and site profile review was really necessary before we could adequately handle these petitions.

I think there's issues we've raised, you know, repeatedly about defining sufficient accuracy, and this all comes back to this particular instance we're dealing with today, but we obviously don't have time today to sort of reformulate the policy. We need to deal with this petition first. But I would certainly urge us to -- and NIOSH to consider sort of the future and how we can better handle these situations, what procedures we need to put in place, do we need to develop better criteria, et cetera, because what you said about equity I think is also important. But when we're sort of going along from case to case, we have to sort of do as best we can.

DR. ZIEMER: Okay, other comments or does anyone wish to speak for or against the petition -- for the motion, rather? Wanda Munn.

MS. MUNN: I just -- I also am not speaking specifically to the petition. We've heard already this morning many issues that have -- that we faced and some of the stumbling blocks that we've had to try to crawl our way over. Not very much has been said about those

stumbling blocks and how they have been addressed. It might be wise for us to recall that at our last meeting we specifically outlined for NIOSH information that we wanted from them, in effect proving that they could do what we had asked to do; which is, give us prove that you can do the reconstructions that need to be done with the information that you have at hand.

They did that, and to all appearances did that very well. The fact that information can -- continues to develop does not change the fact that they have in fact shown they can do that; that is to say, they have shown that they can do dose reconstructions on this group of workers given the information that they have, a fact I think we should bear in mind.

DR. ZIEMER: Okay, thank you. Let me give others a chance to talk. Mark Griffon.

MR. GRIFFON: I guess I -- just going back to Gen's comment about sufficient accuracy -- and I've been grappling with this as I've gone through this, too, but I mean part of where I've seen this evolve is that it's really apparent to me now that when it comes down to

being able to calculate dosage for individual claimants, we're -- instead of having this massive amount of data that we're relying upon, we're down to smaller sets of data with very limited information on how that's distributed from an isotope standpoint. So we've got this air data, together with the residue information on the fractions from the residues, and that's driving a lot of the dose. There's other factors in here, obviously, but when you look at some of the cases, a lot of these things are now being driven by that.

So all of this information on uranium urinalysis, to some extent the individual radon breath data, we're not relying on that anymore. So now we're -- and as we've gone through this, at least my feeling, my sense has been that each time we've asked for a refinement -- there's been a massive amount of work that's gone into this, but where there's a -- where there's a problem it's ended up that certain critical information is not available so that they're defaulting to -- it's not just a claimant favorable approach, it's that there's certain information critical to the first

method that wasn't available that limited them. And I'm saying that that is my reason for saying, you know, at some point you've got to say there's just not sufficient data and it's not -- you can't make an accurate estimate on -- for all the claimants on their dose systems in this site. You can't just come back with a higher number and say, well, we're being claimant favorable because critical information was missing to support your first sort of method.

I guess what I -- what I -- where that really came true was, you know, we rolled around to using this linchpin sort of -- of a method became the radon breath data. So we all spent a lot of time going into that and looking at that and listening to the method description, and then we had a discussion of the residues and the fact that they weren't all K-65, but there was this AM-7 and how would that -- you know, that's got a different ratio of thorium to uranium -- could potentially affect things. The real answer is yes, you get higher numbers when you use the thorium error combined with this thorium residue fraction, but the reason

they went in that direction was they couldn't tell which -- what people were dealing with AM-7 or K-65 or a mixture of regular uranium. So they had to default -- you know. So at some point you've got to say that there's critical elements that are missing that are making this impossible for us to do an estimate with sufficient accuracy.

I know that I'm grappling with how we define that, too, but that's what I've kind of -- I've felt like this has evolved with -- with these -- with these patches to sort of -- okay, this method didn't -- we're missing a critical element in this method so let's go on to this one, and we can argue that it's -- you know, they're higher doses, so it's more claimant favorable. But I think -- and now we're down to -- the first presentation we saw we had great amounts of information on urinalysis data, we had air sampling data which could help us as a reality check to bound these doses, all this urinalysis data -- I mean, it might contribute a little dose for the uranium, but to much extent it's gone as far as the critical dose consequence elements in this equation.

So you no longer have all this individual data that you're going to reconstruct doses with. You're back to gross air -- gross alpha air sampling, multiplying by a fraction, and from what I see from a spreadsheet I got yesterday, you know, some of these -- I'm not -- we haven't had a chance to review how these fractions were developed, but I mean, there's not a ton of data. Certainly these fractions were not -- were not based on isotope analysis done in the plant. They were -- they were sort of after the fact from the residue material. So, you know, you're down to a few. You know, you've got gross air alpha sampling and fractions which we've got a couple of values for, that's hinging the whole -- that's driving the whole -- at least a majority of the dose consequence, I would say.

So I think that's what I'm saying that we've lost our ability to be sufficient and accurate on all the dose reconstructions for this cohort.

DR. ZIEMER: Let me make an observation here because there's been an implied criticism of the change in methodology by NIOSH. But let me

point out that that change in methodology was largely driven by the recommendations of our contractor to consider some other issues. And in fact had they been responsive to that, I think we would be criticizing them for, for example, digging in their heels and sticking with the original data.

What we've seen emerge is almost a kind of new methodology based on some considerations that SC&A has asked be looked at, and obviously they are considerations that have substantial implications on dose. In fact, although the estimations now that come out of that look like they're relying less on original data, I think the resultant doses, in most cases, maybe in all cases, are substantially higher than would come out of the original datasets. And in that respect there is certainly a much more claimant-favorable effect for the dose reconstruction.

Okay, Jim, you have another comment?

DR. MELIUS: Again, I don't think there's any attempt here to downplay the efforts that NIOSH has made, and I think I, and I hope others would, appreciate the great amount of effort

they've put into it and their integrity in dealing with many of these issues. We -- in one sense, you know, us getting a spreadsheet last night, you know, finally to see some data is -- this makes it difficult. At the same time they have been honest enough to continue to make efforts and to work on this and to share that information the best we can.

But I still think the bottom line comes down -- it's where I disagree with Wanda. I don't think that they've shown that they can do individual dose reconstruction with sufficient accuracy. They have addressed some of the points that we asked them, but we've only -- as Mark has just pointed out, we've only uncovered more issues, more things that need to be resolved. And I think we have to look at it at this point in time and I'm certainly not satisfied that they can, you know, do dose -- individual dose reconstruction with sufficient accuracy. And I think on that basis we need to, you know, pass and that -- this motion.

DR. ZIEMER: Anyone? Robert Presley.

MR. PRESLEY: I agree that, yes, the people that work at Mallinckrodt were hurt, but some

of the things that have gone on about the concern of the angle of the instrument, of the badge. We have over 60 years of industrial hygiene data that has gone on, and today the best place to wear your badge is still upon the upper portion of the torso of the body because they feel like that that's where you get the average dose. And so I question this thing about the angle of the badge, but I feel like that -- under the law, that NIOSH has stated that they have enough information to do dose reconstruction. And under our charge, that is what the law says, that we -- if they say they have it, then we go back and accept that. Thank you.

DR. ZIEMER: Okay, Henry Anderson.

DR. ANDERSON: I mean I think there's been tremendous advances made since the last meeting, and I would just remind -- they told us they could do it using the old data and they could, and we raised -- I mean we were -- we were very close at the last meeting to saying they could do it using the methodology that's still on the table, and now in response to our concerns and our issues that weren't really

there in the first methodology, and we were told that they would very promptly be able to do all of these in a very short period of time, and they would not just -- I mean, my feeling is this probably would -- this issue would not have been raised, we would not have the modeling and the new methodologies that they developed if we had not have held our ground and said we want to -- you to show us that you can do that.

And so I think we've had tremendous advances. Again, it's moved to a recognition or an appreciation that the thorium was more important than it was previously realized, and that is an advance and that will carry over into their evaluation and understanding of other circumstances elsewhere. So it's not as though this time, effort and resource has been needlessly expended. I think we've advanced it. I think the difficulty, to me, is -- for this particular one -- this has been a learning exercise and when we started it there was a great deal of information not available. It's now become available and, again, the kind of source that we saw in the cases appears in many

of these instances to be this thorium issue, and I think that's still very new and new data is coming and at some point I think it could -- given enough time and resource and effort, this could become a very real robust model if there was sufficient data available, but I think in this particular instance there I think still appears to be a paucity of what we need, and we need to move on. We can't expend all our resources. There's other issues that will come up and this will be of benefit to us in understanding what those exposures might be.

DR. ZIEMER: Okay, so you are speaking for the motion, I think.

DR. ANDERSON: I think we need to draw to a close --

DR. ZIEMER: Okay, okay.

DR. ANDERSON: -- don't have a revised --

DR. ZIEMER: Thank you. Is anyone speaking against the motion?

(No response.)

Then the Chair will exercise his prerogative and speak against the motion. The -- and there are many things that are said here that I do agree with. However, I believe that the Agency

and our contractor have both demonstrated that dose reconstruction indeed can be done.
Our contractor has agreed, at least in principle, that it can be done. They have cautioned on a selection of a number of parameters that go into this and how those are selected, such as the -- the DR factors and others. But nonetheless, the issue of can you dose -- do dose reconstruction, in my mind you can, based on what I've seen. The sufficient accuracy issue, of course, is a hard target. The accuracy that's required is an accuracy for making a decision on compensation. In fact, in most cases we do not claim that the numbers are accurate. You could not do epidemiological studies from the numbers that come out of this program. I'm not just talking Mallinckrodt but in general, because there are -- in many cases are intentional overestimates because of claimant-favorable considerations. So in my mind we can do dose reconstruction with sufficient accuracy to make a fair decision for claimants in this case.
Also, I'd simply point out, and this often will appear to be a discrepancy and we simply alert

you to the fact that -- and I think there's a statement in here that in essence suggests that those who -- if we go to Special Exposure Cohort, those that are not successful in that then move back to dose reconstruction, which we say earlier we really can't do very well, if we accept this. So there is a contradiction of sorts in the document that I would certainly be uncomfortable with.

But my bottom line here is -- and I agree with everything on the timeliness. I think we have to make a decision and, you know, the Chair is -- I'm quite comfortable with moving ahead with whatever this Board decides, you know that. But I feel obligated to say that, in spite of the limitations that we see, there's a vast amount of data here and good dose reconstructors can, in my mind, reconstruct doses for purposes of making fair decisions for workers. And I -- I would judge that in probably almost every case, if we did have dose reconstruction, because of the parameters that have emerged out of this kind of new methodology which makes use of and takes into consideration particularly raffinates, that

these will be highly claimant favorable.
So I'm speaking against the motion, Dr. Melius.
Now, you get a chance -- who's next here?
DR. MELIUS: Mark or Leon, I'm not...
DR. ZIEMER: Mark -- Leon, yes, you're next.
Okay, Leon, please.
MR. OWENS: Dr. Ziemer, I speak in favor of the motion, and not just because I seconded it.
But I think that Dr. McKeel spoke of a segment of workers who have not been or who were not monitored, who are not represented based on any of the data that we are considering. And so in order to perform dose reconstruction, whether we rely on coworker data for this segment of workers who would be claimants, I'm very concerned -- troubled by that, for us to say that we can accurately perform dose reconstruction on this group of workers when in fact we have a sizable segment of those workers who were not even considered at all.
I think also when we look at the timeliness issue that was brought up, the discrepancies in some of the studies, it lends itself toward granting a Special Exposure Cohort for these workers.

DR. ZIEMER: Okay, thank you. Is Mark -- are you next?
DR. MELIUS: I think Mark was next.
DR. ZIEMER: Mark and then Gen and then Jim.
MR. GRIFFON: Just a couple of points to follow on what you said, Dr. Ziemer. I guess there is this procedural question, too, that we have. I don't think that we asked or that we could ask SC&A their opinion on this SEC because they are only doing a site profile review, and I think this was one of the problems that we've discussed on here and that's why we have a new task forthcoming. So I don't think they weighed in and actually kind of gave us --
DR. ZIEMER: And you're correct with respect to the petition, they did not, yes.
MR. GRIFFON: Right, right.
DR. ZIEMER: I'm -- I'm characterizing their characterization of what NIOSH said it could do in terms of those items that we asked them to address, right.
MR. GRIFFON: Okay. I guess -- I mean, I think some things we heard from them was that a lot -- a significant amount of work and things like that, but --

DR. ZIEMER: Well, I'm basically quoting from items in their report where they agreed with -- that in principle NIOSH could do what it said, and then they cautioned on a number of these things and -- I mean --

MR. GRIFFON: Anyway --

DR. ZIEMER: Yeah.

MR. GRIFFON: -- the other point you made earlier, Paul, was that we had asked for -- actually, that the Board's questioning had resulted in some of these newer models, and I think I would disagree with that. I think, at least my -- and it's been -- I don't know how many meetings we've had on this so I might be a little confused on the timeline, but my remembering of this is that we asked for clarification of the approach, and then we got down to specifically saying, well, can we see a couple of examples in how you're going to apply this.

And my sense, having put a lot of hours into this myself, is that when everybody went back and dug into the weeds -- which is where, by the way, from the beginning of this program I've said we might want to look on certain

sites -- they realized that there were some problems with their initial model. And I don't think we asked them to come back with a radon breath model, per se. We said consider people who have radon breath data, because they had talked about it as maybe a bounding condition, or maybe -- in earlier discussions I remember it being discussed as a way to identify who were residue workers and who to apply different fractions to than other people, non-equilibrium versus equilibrium.

So I don't think we asked them for a new method. I think --

DR. ZIEMER: Oh, no, we didn't ask them for that, no.

MR. GRIFFON: -- after further examination we realized --

DR. ZIEMER: I think it grew out of that, yes.

MR. GRIFFON: I guess my point is that after further examination they realized that the data wasn't sufficient to support their existing method and they went to another proposal. That's at least my feeling at this point.

And I also -- and I do -- I do appreciate all the work. I've been doing a lot of work with

these guys and I appreciate the massive amount of time that's gone into this. And I also think at the end of the day here or in the next meeting -- real soon we have to work out the process stuff, the policy questions, and we have to have an evaluation process, I believe, for our Board so that NIOSH understands what they're going against. And I think that's -- that is an important step I think we need to take.

But at this point, you know, that's my feeling, is that we didn't ask for a new model. I feel like there wasn't sufficient information on their initial evaluation report that was before the Board, that they couldn't support that in the depth that they first thought they could, and then they came up with a variation on the model.

DR. ZIEMER: Uh-huh.

MR. GRIFFON: And I don't know that -- I mean it results in higher doses, and you could say well, that's claimant favorable. I see it as they didn't have sufficient data to support the first model so they default to a sort of -- a different approach in the higher -- and you

have higher -- higher doses at the end of the day. I'm not sure that answers that question of sufficient accuracy. That's my opinion.

DR. ZIEMER: Okay, Gen Roessler.

DR. ROESSLER: I know you're looking for an indication of how we're going to come down on this, so I will say that I'm going to vote against the motion. On an emotional level I don't want to do that. I think these petitioners have been through a horrible situation because of our learning curve, the very first one. But I think on an actual basis, the things that bother me are the uniformity, how do we continue on in this process -- and I brought that up before -- so that every claimant is treated equally. And I think about the claimants who maybe can't go through the SEC process or the claimants who don't have the support group and the amount of effort that went into supporting them that these claimants have had. And so keeping that in mind, I just can't feel comfortable with voting for the motion on this particular petition.

DR. ZIEMER: Okay, thank you. Jim Melius.

DR. MELIUS: Yeah, I'd like to make three points. One is, and I believe I said this at the last meeting also, that I think one of the things we need to be careful with if we try to guess at what we think -- whether or not we think NIOSH can meet the criteria and do appropriate dose -- individual dose reconstruction was that if we get to the point where we then -- I mean, our next sort of evaluation is when we would look at individual dose reconstructions. And after putting people through this process for over a year, if we got to the point and it turns out that we weren't satisfied with how NIOSH was doing those, I mean it would make us look pretty foolish and it would be, you know, grossly unfair to the claimants. And I think we tried to pursue that issue to some extent with the example cases and I think to some extent that that was helpful; though, given all the other changes that have taken place and sort of how we've approached this dose reconstruction, I'm not sure that we ever really were able to take full advantage of that.

The second point, you mentioned about the

utilization of these data for epidemiological studies. Well, on one hand you're correct in terms of claimant favorableness would not make it appropriate for such use, but on the other hand the test for use in an epidemiological study is you're looking at group data. And our -- you care about whether one group of workers with a particular type of exposure and so forth had increased risk. You don't focus as much on the individual person; whereas, we are charged with evaluating -- this data is sufficient for individual dose reconstruction with sufficient accuracy. And I think that's some ways a different test. And so as the utility of this data for epidemiological studies or I just -- I don't think that's a relevant criteria. Finally, the section on the ability to do dose reconstruction with -- for external doses, I think it was an issue that the petitioner raised. I believe we've had some partial discussions of this before. I think we were actually scheduled to have a more complete discussion last meeting and ran out of time, 'cause I think it's a -- it is a difficult issue on non-SEC cancers and what's done with

them. I was trying to construct something here that was narrow and that dealt with the particulars of this case and was a statement, not making -- not trying to make a broad statement about what should be done with -- about individual dose reconstruction for non-SEC cancers. I think that is something we need to take up as a policy issue of this Board in a more general sense, and that NIOSH and Department of Labor need to wrestle with in the context of the program and the law.

But to me, I think that this narrowly-defined exception is appropriate and is helpful and it is -- again, this letter is designed to convey our understanding of the situation at this particular point in time.

DR. ZIEMER: Okay, thank you. Other comments, pro or con? Yes.

DR. MELIUS: I also need to make one friendly amendment to my own motion --

DR. ZIEMER: Oh, all right.

DR. MELIUS: -- which is a correction in -- just for the record, in the second paragraph, the third line from the bottom -- this is the boilerplate language -- the -- after -- the

first two words on the third line from the bottom are "this employment" and there should be a --

DR. ZIEMER: Comma? Oh, or --

DR. MELIUS: -- "or in combination".

DR. ZIEMER: "Or in combination." Yes.

MR. GRIFFON: There's some other typos, too.

DR. MELIUS: I know there's some others. That one was, I think, the most legally important or whatever.

DR. ZIEMER: Other -- yes, Dr. Roessler.

DR. ROESSLER: While Jim is looking at the wording -- I guess I'd better use the microphone.

While Jim is looking at the wording, I have a question that -- some of the wording seems like a contradiction. In the second to last paragraph you say, second sentence, "It should be noted that the Board believes that the exposure information available was adequate for the reconstruction of external exposures."

That seems to be a contradiction to your bullet on the first page, and that's the fourth bullet where you talk about --

MR. GRIFFON: Yeah.

DR. ROESSLER: I think I'd like that clarified. I don't know if anybody else --

DR. ZIEMER: Well, I referred to that indirectly before, that there is a kind of built-in contradiction here that on the one hand we say you can't do them very well and on the other hand we're saying that they should be done in these cases. So it's a -- and I might suggest, while you're -- while we're talking about that -- again, I've indicated that I oppose the motion, but nonetheless let me try to help you improve it.

In fact, although the angular thing has been brought up, it actually is not that difficult of an issue to deal with. I -- I mean, you've characterized it, but people have been dealing with that angular issue for decades and it actually is not hard to convert to organ dose, even in cases where you really don't know what the angles were a priori.

So you might say that there are concerns about it; I don't know how serious they are at this point. I honestly -- certainly within -- within monitoring -- you know, personnel monitoring is not like measuring doses for

therapy where you have to know that dose within one percent. Most health physicists are happy if you're within, what, plus or minus 20 percent, Mark, would you say? I mean, for field work.

MR. GRIFFON: Definitely, yes.

DR. ZIEMER: Right. And within the uncertainties of what is present in many of the dose reconstructions anyway, I would offer that the angular incidence issue, if one were doing dose reconstruction, is much more readily handled than implied here. I'm not even sure that that particular bullet adds to the argument, the main argument, and it certainly contradicts or weakens the suggestion that you have later in the document. I simply offer that up as a friendly --

MR. GRIFFON: Yeah.

DR. MELIUS: I think Mark...

MR. GRIFFON: I tend to think that -- you know, we -- we felt -- I mean, the reason we have that -- I see it as -- how you could read it as contradictory, I guess --

DR. ZIEMER: I just don't think it's a showstopper.

MR. GRIFFON: Right, it was a point that's not -- it was a point that's not resolved, but the reason we have that final paragraph in is, I felt, basically that it's pretty readily resolved and they're going to do it because it's a program-wide effect.

DR. ZIEMER: It's not a showstopper and I think for those who support this motion, you are doing yourself a disservice to have both of those in there, I'll simply tell you that.

DR. MELIUS: I would point out that what disturbed me was -- you know, when this issue was raised, NIOSH's defense -- and not that this is inappropriate but it made it more difficult for us -- was well, it wasn't one of the six points so they weren't going to deal with it.

DR. ZIEMER: No, let me say that Jim indicated they would deal with it, but it was not one of the six things they asked us to come back with information on.

DR. MELIUS: Let me clarify, then. Jim's response was he wasn't going to deal with it in this meeting.

DR. ZIEMER: Oh, yeah.

DR. MELIUS: And so we're sort of left hanging with that, and then we hear that they haven't -- they may or may not -- there's a technical bulletin of some sort that's still under review someplace or still being written. I have no --

DR. ZIEMER: Maybe we would like to hear either from NIOSH or ORAU, but Dick Toohey or Jim Neton, do you agree that the angular incidence thing is not a showstopper for dose reconstruction or --

DR. NETON: Yes, yes, I agree with that position. It's a matter of degree of what the collection factor is, but it's -- I think it can certainly be bracketed.

DR. ZIEMER: But it's certainly much smaller than other uncertainties in this proposed dose reconstruction methodology.

DR. NETON: Yes, I agree with that.

DR. ANDERSON: I mean, basically it's an uncertainty --

DR. ZIEMER: But there's a lot of uncertainties that are much -- if you're going to start mentioning them, this is not one that should be highlighted. I'd simply offer that up. I mean you're welc-- the Board can do what it wishes

on this, but I believe that the contradiction is still built into the motion if...

Any other comments? Yes, Michael.

MR. GIBSON: I tend to disagree with that opinion only because on the few times that we've -- people were monitored, right, at least at the Mound facility, when they knew that there was going to be radiation built from different angles. They would strap a dosimeter on our forehead, they would strap dosimeter rings on our fingers, or our thighs and every part of our body. So if the angle of the dosimeter isn't important, why would they go the extra steps at times to add all these other dosimeters?

DR. ZIEMER: Okay, thank you. Other comments?

DR. MELIUS: I would just -- in response I think I would accept as a friendly amendment from an unfriendly source --

DR. ZIEMER: Hey, I'm always friendly.

DR. MELIUS: -- the -- let's take out "serious" and leave that. I would prefer to leave that in as an uncertainty, recognizing --

DR. ZIEMER: "There are concerns"?

DR. MELIUS: "There are concerns."

DR. ZIEMER: Is that -- the seconder agree to that change?
MR. OWENS: Yes, sir.
DR. ZIEMER: Then without objection the motion is changed to take that into account. Any other comments, pro or con?
DR. MELIUS: And I would also offer -- in response to your comments, whether friendly or unfriendly here -- in the second to last paragraph I think it would be a little bit more clear, in the third sentence, it would be the third line, "information available to adequately (unintelligible) reconstruction of individual external exposures."
DR. ZIEMER: For the --
DR. MELIUS: And where appropriate for --
DR. ZIEMER: Well, yes. Of course, I think the "individual" actually is implied, but there's no reason not to add it, and without objection add the word "individual."
Okay. Any -- it's second to last paragraph, third line would now read "adequate for the reconstruction of individual external exposures."
Any other comments, pro, con, or otherwise?

Friendly, unfriendly, nasty, really friendly?

(No responses)

Then can I assume that the Board is ready to vote on this motion?

UNIDENTIFIED: (Off microphone) I call for the question.

DR. ZIEMER: Okay, the question is being called for. I'm going to ask for a show of hands. Those who favor the motion, please raise your right hand. Okay, we've got Owens, Melius, Espinosa, Griffon, Anderson, and Gibson. And those who oppose the motion, Roessler, Munn, Presley, Ziemer.

The motion carries and the recommendation will be made to the Secretary to support the -- or to support the petitioners. I believe -- and let me -- and we will follow the regular procedure and generate the letter.

And let me point out again to those here assembled that this is a recommendation that accompanies the NIOSH recommendation, the NIOSH recommendation is that dose reconstruction be done. So both recommendations now will go to the Secretary, and then the Secretary will take both into consideration. The Secretary of

Health and Human Services makes the decision. The Board does not make the decision, we make a recommendation. The recommendation of this Board then is to support the petitioners. It is so ordered. Standing ovation of one.

MR. GRIFFON: Paul, could I --

DR. ZIEMER: Comment, Mark.

MR. GRIFFON: I just wanted to say I have a few typos which I'll just provide. They're not substantive.

DR. ZIEMER: We will take care of the typos. We will take a break now and then reconvene in about 15 minutes.

C E R T I F I C A T E OF COURT REPORTER

STATE OF GEORGIA

COUNTY OF FULTON

I, Steven Ray Green, Certified Merit Court Reporter, do hereby certify that I reported the above and foregoing on the day of August 26, 2005; and it is a true and accurate transcript of the testimony captioned herein.

I further certify that I am neither kin nor counsel to any of the parties herein, nor have any interest in the cause named herein.

WITNESS my hand and official seal this the 7th day of September, 2005.

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STEVEN RAY GREEN, CCR

CERTIFIED MERIT COURT REPORTER

CERTIFICATE NUMBER: A-2102